THE DRUGS DON'T WORK

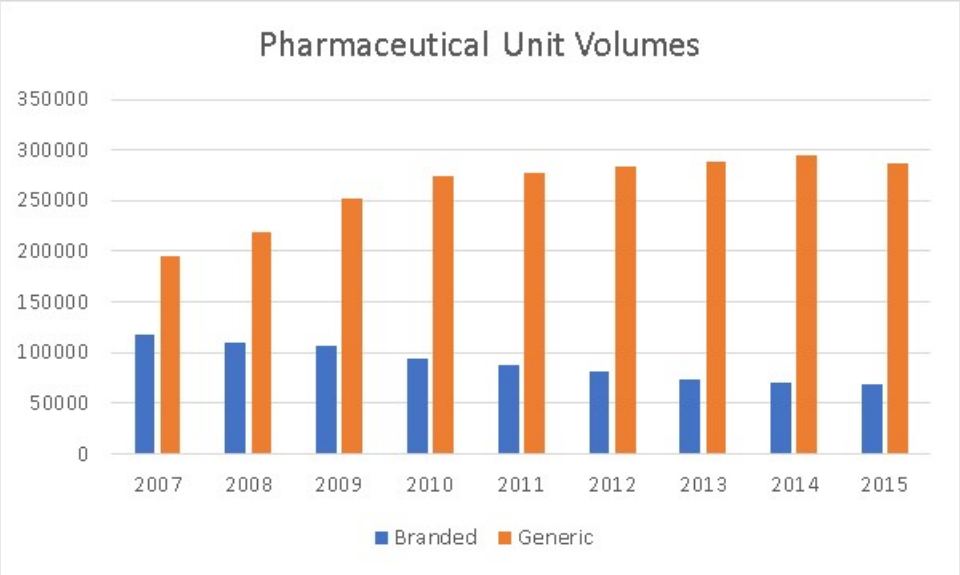
The US Healthcare system is truly extraordinary. Per capita spending on healthcare is double the levels seen in most other developed countries. This is in part driven by a very different set up. Key differences are the private sector has far more freedom to market drugs directly to consumers, and Medicare (a federally run health program for the elderly), the largest buyer of drugs, is prohibited by law from negotiating lower prices. The result is that the US has higher prices for drugs, and due to the extra spend, also has the most innovative drug market. It can be argued that the US subsidises drug development for the rest of the world. However, recent increases in drug prices seem to have been driven by regulatory changes due to the Affordable Care Act (Obamacare), rather than market forces.

Healthcare Expenditure per Capita; USD PPP terms 2015				
Country	2012	2013	2014	2015
United States	8423	8617	9024	9451
Germany	4695	4922	5119	5267
Sweden	4860	5003	5065	5228
Canada	4320	4503	4492	4608
Australia	3808	4177	4207	4420
France	4063	4292	4367	4407
Japan	4017	4152	4152	4150
United Kingdom	3192	3881	3971	4003

Source: World Health Organisation

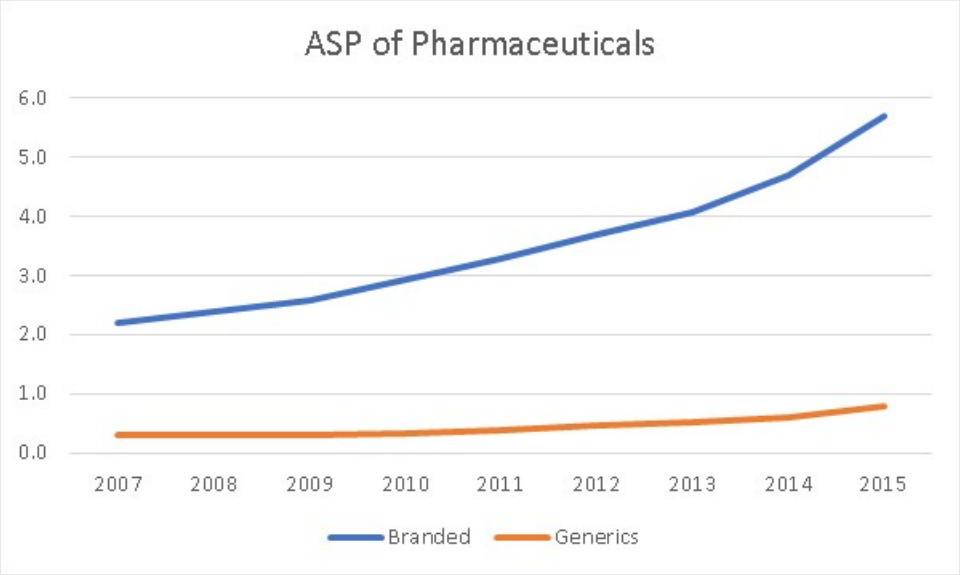
In 2016, total US health expenditure was USD 3.3 trillion; US citizens directly paid (out of pocket) USD 350bn, with the remainder paid by third parties - USD 1.1 trillion was paid for by private health insurance, with Medicare and Medicaid (a state run health program for individuals on low incomes) paying USD 1.2 trillion and USD 528bn was met by a mixture of other government programs, privately raised funds and charities.

Of the total USD 3.3 trillion spent on healthcare, USD 600bn was spent on drugs, with half on prescription drugs. The other half was spent on drugs used in procedures, and not procured via a prescription. While drug spending has doubled since 2007, we have seen a steady increase in the use of generic drugs at the expense of branded drugs.



However, even as we have seen volumes decline for branded drugs, we have seen an increase in total US dollar spend for branded drugs.

Generic drug spend has also increased significantly in the last few years. Both generic and branded drugs have seen price increases, using the data above we can calculate and USD ASP for branded and generic below.



The above graphs would imply that all prescription drugs, both branded and generic, have seen price increases. However, when we consult data from independent US advisory agency, MEDpac, and the Centre of Medicare and Medicaid Studies (CMS) a different picture appears.

MEDpac looks at Medicare Part D (the part of Medicare that pays for prescription drugs) data from 2009 to 2014. The most striking feature is how the average price for a prescription for a low cost beneficiary (individuals spending less than USD 6154 per annum) on drugs has fallen by 24% over the period, while the average drug cost for high cost beneficiaries has risen by 50% over the same period. (http://www.medpac.gov/docs/default-source/data-book/jun17_databookentirereport_sec.pdf?sfvrsn=0)

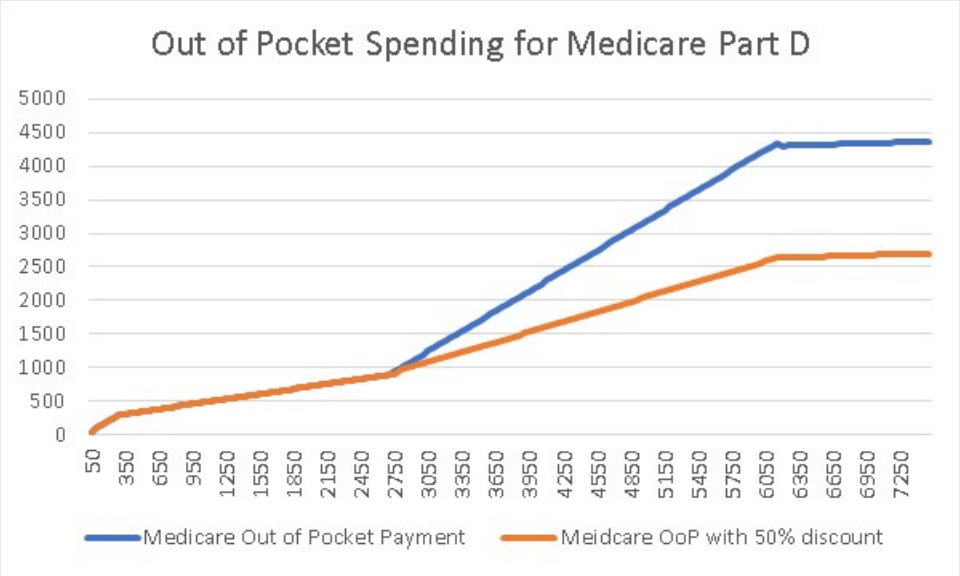
Medicare Part D			
USD Billions	2009	2014	CAGR
Spending per Beneficiary			
High Cost Gross Drug Spending	12294	18845	8.9%
Low Cost Gross Drug Spending	1846	1683	-1.8%
Total Spending			
High Cost Gross Drug Spending	29.2	64.6	17.2%
Low Cost Gross Drug Spending	44.6	56.7	4.9%
Number of Beneficiaries			
High Cost Beneficiaries	2.4	64.6	7.6%
Low Cost Gross Beneficiaries	24.1	33.7	6.9%
Average Price Paid Per 30 Day Prescription			
High Cost Beneficiaries	$110	$166	8.40%
Low Cost Gross Beneficiaries	$42	$32	-3.50%

One of the reasons for the increase in high cost beneficiaries has been the development of a new drugs that cure hepatitis C. The main drugs used here are Solvadi and Harvoni, and according to data from CMS, total Medicare spending on these drugs in 2014 was USD 3.8bn from nothing in 2009. Total high cost spending without the hepatitis C drugs has risen to USD 60.8bn, equal to spending doubling on high cost drugs compared to a 27% rise on low cost drugs. Excluding the hepatitis C drugs, we can see that drug spend rose 14% for Medicare in 2015 from 2014, while it rose 25% for Medicaid over the same period. Given that volumes have been flat, and we have excluded the big spending increase in hepatitis C drugs, the growth in spending has been driven by drug prices.

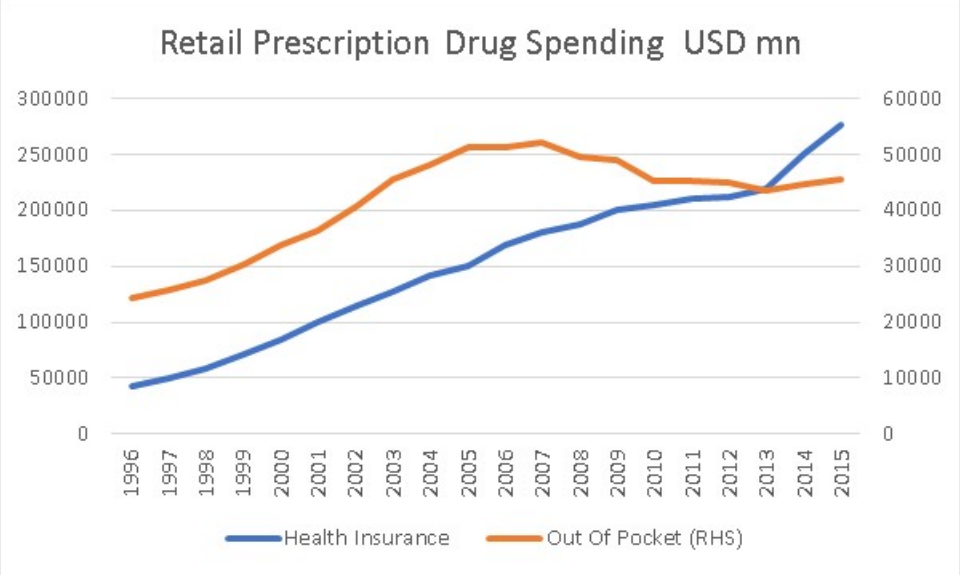
Drug cost increases at Medicare and Medicaid have been driven by long standing issues exacerbated by the changes brought about by Obamacare. Government run pharmaceutical plans such as Medicare and Medicaid are banned from negotiating drug prices with manufacturers. This is at odds with other government run healthcare programs such as the UK's NHS, which use their buying power to drive prices down.

There are two big drivers to recent US drug price increases in my view. Firstly, there has been changes in how Medicare pays for drugs, creating an incentive for drug companies to raise prices and secondly, there has been the increase in the number of "Orphan Drugs", drugs designed for medical conditions that have relatively small numbers of sufferers, being developed. Both factors now look to be coming under regulatory pressure.

For Medicare Part D spending, high cost beneficiaries are defined as those beneficiaries who spend over USD 6154 a year on drugs. Spending in excess of USD 6154 is 95% covered by Medicare. However, the first USD 295 is not covered by Medicare, spending between USD 295 and 2700 is 75% covered and spending between USD 2700 and USD 6154 is not covered by Medicare at all. The gap between USD 2700 and USD 6154 is known as the "Medicare Donut Hole". Changes under Affordable Care Act allowed for some drugs to be purchased at a 50% discount to list price, while the full list price could be counted towards Medicare Donut Hole. Below graph shows the out of pocket spending for a given level of drug spending in US dollars.

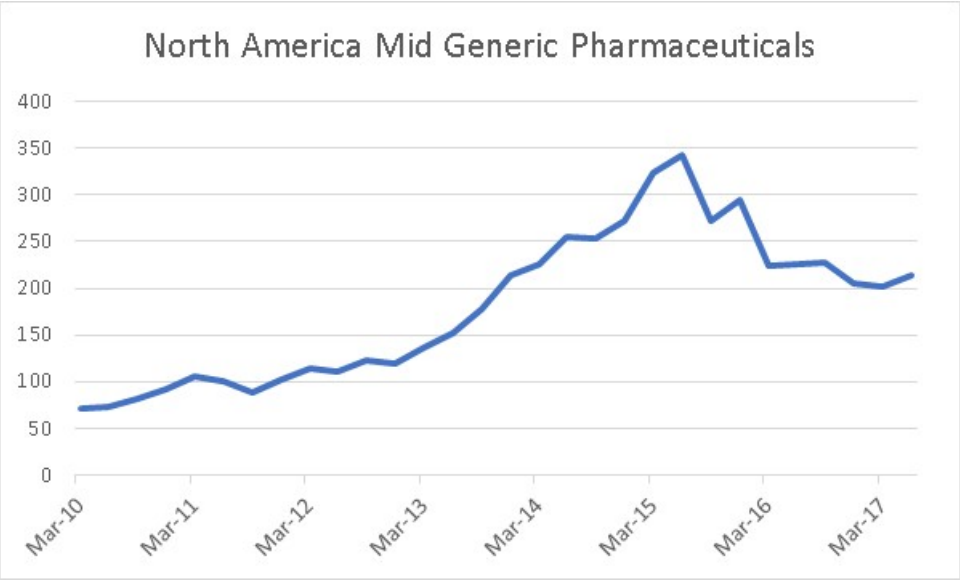


For drugs with little or no competition, prices could be raised without effecting demand; the drug consumer would potentially see marginal prices fall dramatically if this pushed them in to the top tier of Medicare benefits where costs are 95% covered. This can be most clearly seen in the graph below where out of pocket spending on drugs fell even as health insurance spending on drugs rose. According to the 2015 Medicare Drug Spending Dashboard, 29 of the 70 drugs details saw 50% price increase over 5 years. Medicaid saw ever larger number of drugs with big price increases. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015Medicare.html .

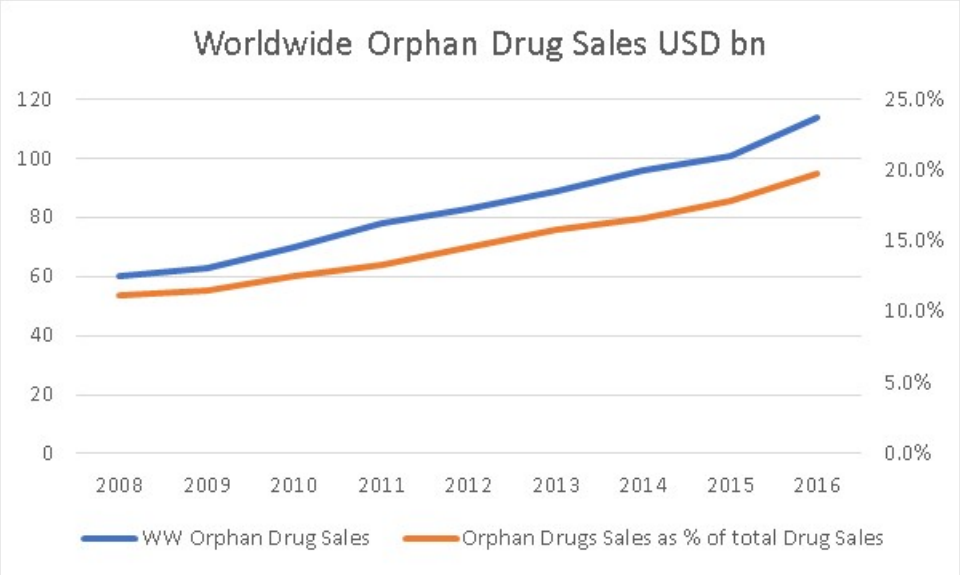


The US Federal Drugs Agency ("FDA") is starting to take aim at rising drug prices, particularly with older drugs that have recently seen drug prices increase by speeding up the approval of generic drugs
https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm

This has a detrimental effect on the share prices of generic drug makers, as increasing competition is being priced in.



In the US, one criteria of an Orphan Drug is that there are less than 200,000 potential patients. If Orphan Drug status is granted by the FDA, 7 years marketing exclusivity is given as well as 50% tax credit on R&D and other grants. The rising market share of Orphan Drugs has also been a big driver of higher costs. According to the EvaluatePharma Orphan Drug report 2017, the average cost per patient of Orphan Drugs is USD 140,000 vs USD 28,000 for non-orphan drugs. The same report notes that Orphan Drug sales now make up nearly 20% of all drugs sales worldwide, up from 11% in 2008.



An issue with the Orphan Drug Act highlighted by this blog post from the relatively new head of the FDA, Scott Gottlieb. https://blogs.fda.gov/fdavoice/index.php/2017/09/fda-is-advancing-the-goals-of-the-orphan-drug-act/ states that Orphan Drug status has been granted for many paediatric treatments. Pre-existing laws intended to stimulate paediatric drug studies, however, the use of paediatric sub-groups to gain Orphan Drug status has actually led to fewer paediatric studies. This would imply that the FDA is looking to greatly tighten up the issuance of this status. Orphan Drug status has conveyed great benefits on the pharmaceutical industry. Firstly, it allows drugs to be tested on smaller populations, greatly reducing costs. Secondly, it has allowed some drugs to be granted Orphan Drug status, but then go on to be used for treatment of much wider patient population. Thirdly, some large pharmaceutical companies have sought and received Orphan Drug status for the some of the best-selling drugs in the world; these highly profitable drugs then received favourable tax credits and exclusivity on marketing for 7 years. The Kaiser Health Network found that about a third of drugs given Orphan Drug approval have either repurposed the drug for all users or have received multiple Orphan Drug statuses to market to different subsets of patients.

Rising drug costs have been one cause of rising insurance premiums in the US, which have risen faster than income and inflation over the last 10 years. The new head of the FDA is looking to foster competition to reverse these effects, and his efforts have already lead to weakness in generic pharmaceutical companies. What were regulatory tailwinds for the pharmaceutical sector are turning into headwinds.

INFORMATION

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